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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/772,445

02/06/2004

Ravi Upasani

1483.0340003

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03/04/2008

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EXAMINER

JAISLE, CECILIA M

ART UNIT

PAPER NUMBER

1624

MAIL DATE

DELIVERY MODE

03/04/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/772,445	Applicant(s) UPASANI ET AL.	
	Examiner CECILIA M. JAISLE	Art Unit 1624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 February 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 18-34 is/are pending in the application.
- 4a) Of the above claim(s) 24-34 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 18 and 19 is/are rejected.
- 7) ☒ Claim(s) 20-23 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>08-20-2004</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED OFFICE ACTION

Information Disclosure Statement

Applicants' attention is invited to the documents lined out on the attached PTO-1449, copies of which could not be located in the parent files. If Applicants wish these documents to be considered on this record, they must provide copies thereof.

In addition, the citation to document AS5 should be corrected to indicate that this is from the *Journal of Neurological Sciences*, not the *Journal of Neuroscience*, as the current citation would suggest.

Restriction

The restriction requirement set forth in the Office Action of Sep. 10, 2007 is withdrawn.

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 18-23, drawn to Formula III compounds, where R7-R6 taken together are any of the groups recited in claim 19, that is, -OCH₂O-, -OCH₂CH₂O-, -O-CF₂-O-, -CH₂CH₂CH₂-, -CH₂CH₂CH₂CH₂-, -OCH₂CH₂-, or -N(R₉)-CO-O-; where R₉ is optionally substituted lower alkyl, classified in class 544, subclass 234, and their pharmaceutical compounds, classified in class 514, subclass 248.
- II. Claims 18-21 and 23, drawn to all other Formula III compounds, variously classified in 544, and their pharmaceutical compositions, variously classified in class 514.

III. Claims 24-34, drawn to pharmaceutical methods using Group I, classified in class 514, subclass 238.

IV. Claims 24-34, drawn to pharmaceutical methods using Group II, variously classified in class 514.

The inventions are independent or distinct for the following reasons. Inventions I – IV, respectively, are not obvious variants of each other, i.e., a reference that could be used to reject one invention could not be used to reject another invention; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j).

In the instant case, the Groups I and II compounds are distinct from the pharmaceutical methods of Groups III and IV, respectively, because the Groups I and II compounds would be expected to have different utilities. For example, the Group I compounds would be expected to be useful as muscarinic antagonists (WO 98/00412). The Group II compounds would be expected to be useful for treating or preventing $\alpha 4\beta 1$ adhesion mediated conditions (WO 98/58902).

In the instant case, the related inventions of Groups I – IV, respectively, do not overlap in scope because the inventions of Groups I – IV have acquired separate status, as evidenced by their separate classification in the art. Although some of these Groups may have the same patent classification, they would each require a separate search in the literature. Therefore, it would impose an undue burden on the examiner to search and examine these distinct inventions together.

Restriction for examination purposes as indicated is proper because all these inventions listed in this action are independent or distinct for the reasons given above and there would be a serious search and examination burden if restriction were not required because one or more of the following reasons apply:

- (a) the inventions have acquired a separate status in the art in view of their different classification;
- (b) the inventions have acquired a separate status in the art due to their recognized divergent subject matter;
- (c) the inventions require a different field of search (for example, searching different classes/subclasses or electronic resources, or employing different search queries; see MPEP § 808.02);
- (d) the prior art applicable to one invention would not likely be applicable to another invention;
- (e) the inventions are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

Applicant is advised that a complete reply to this requirement must include (i) election of an invention to be examined even though the requirement is traversed (37 CFR 1.143) and (ii) identification of claims to the elected invention.

During a telephone conversation with Mr. Joseph S. Ostroff on Oct. 10, 2007 a provisional election was made with traverse to prosecute the invention of Group I, claims 18-23. Applicant must affirm this election in replying to this Office action. Claims 18-23 are under examination to the extent that they are directed to the elected subject

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matter of Group I; otherwise, they are withdrawn from examination. Claims 24-34 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

If the reply does not distinctly and specifically point out supposed errors in the restriction and election of species requirements, the election shall be treated as without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which new claims read on the elected invention.

Should applicant traverse on the ground that the inventions are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicants are reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

The examiner has required restriction between product claims (Groups I-II) and method claims (Groups III-IV). Where applicant elects claims directed to the product

and product claims are subsequently found allowable, withdrawn method claims that depend from or otherwise require all limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected method invention must require all limitations of an allowable product claim for rejoinder of the method invention.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined claims will be withdrawn, and the rejoined claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and method claims may be maintained. Withdrawn claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, **applicant is advised that the method claims should be amended during prosecution to require the limitations of the product claims. Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the examiner withdraws the restriction requirement before the patent issues. See MPEP § 804.01.

Rejections Under 35 USC 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 18 and 19 are rejected under 35 USC 102(b) over Haider, Heterocycles (1995), 41(11), 2519-25 (cited by Applicants), describing RN 173463-57-5, 1H-Cyclopenta[g]phthalazin-1-one, 2,6,7,8-tetrahydro-4-phenyl-; and RN 173463-59-7, Benzo[g]phthalazin-1(2H)-one, 6,7,8,9-tetrahydro-4-phenyl-.

Objected Claims

Claims 18 and 20-23 are objected to as directed to both elected and non-elected subject matter. They should be amended to be directed only to the elected subject matter of Group I as set forth above.

Claims 20-23 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CECILIA M. JAISLE, J.D. whose telephone number is (571)272-9931. The examiner can normally be reached on Monday through Friday; 8:30 am through 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

**/James O. Wilson/
Supervisory Patent Examiner
Art Unit 1624**

CECILIA M. JAISLE, J.D.